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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/535,314	03/24/2000	Gary Bridger	391442003700	2416

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/30/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/535,314

Applicant(s)

BRIDGER ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-7, 12-13, 51, 55-58, 98, 102 and 119 -132 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-7, 12-13, 51, 55-58, 98, 102 and 119 -132 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' response, which included amendment claims 1-4, 6-7, 12-13, 51, 55-58, 98, 102 and addition of new claims 119 -132, filed on 5/2/2002, is made of record.

Claims 1-4, 6-7, 12-13, 51, 55-58, 98, 102 and 119 -132, are now pending.

In view of applicants' response all 112 second paragraph rejections made in the previous office action have been obviated. However, the following rejections apply:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-7, 12-13, 51, 55-58, 98, 102 and 119 -132, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Claim 1 and other dependent claims are indefinite as it is not clear whether it is a compound claim or a composition claim comprising the compound and a pharmaceutically acceptable salt. Note the last line of the claim 1 recites "and pharmaceutically acceptable salts thereof" which is an improper Markush if the claim is meant to be a compound claim. Replacement of "and" by "or" would obviate this rejection. Note also the singular-plural mix-up. In addition, note the same apply to "any stereoisomeric forms and ..... thereof".
2. Recitation of the terms "comprises" and "comprising" in the definition of heterocyclic group in claims 12, 56, 58, 125, 129, 131, renders these claims

indefinite as the transitional phrase "comprising" is open-ended and can include more than what is being positively recited therein. See MPEP 2111.03 which states: The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495,501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 7 and 102, 119-120 and 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowles et al. US 5,563,151 for reasons of record.

This rejection is same as made in the previous office action but now includes additional newly added claims.

Applicants arguments to overcome this rejection citing Jones and In re Baird has been considered fully but deemed not persuasive. Following reasons apply.

1. With regard to the 103 rejection unlike Jones relied on by the applicants, the instantly claimed species are within the Markush recitation of moieties intended as substituents on bicyclohetero ring taught by Bowles et al.
2. Furthermore, contrary to applicants urging, the compounds taught by Bowles et al. differ in not having a direct bond. As noted before, the reference differs from the instant claims in not exemplifying compounds wherein Q is a bond not a CO or SO<sub>2</sub> as seen in examples 1-149.
3. There are 149 examples taught by Bowles et al. Hence there is adequate guidance for one to make direct bond compounds. See In re Burckel 201 USPQ 67, which states " Reference must be considered , under 35 U.S. C 103, not only what it expressly teaches but also for what it fairly suggests; all disclosures of prior art, including unpreferred embodiments, must be considered in determining obviousness."
4. Unlike Baird, close prior art compounds are not more complex in structure than the compounds claimed herein as they mainly lack a direct bond for Q
5. As utility, applicants argument that the instant utility is different from Bowles et al., does not render applicants compounds novel or unobvious. The discovery of an additional use not disclosed in the reference does not make otherwise

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obvious compounds unobvious. See In re Best 195 USPQ 430. Furthermore, 103 rejection is being applied only to prior art compounds and one trained in the art would be motivated to make these compounds for the use taught in the prior art.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compound of formula I with W, Z, Q, R1, R2, R3, and B. including Q as a bond, U as hetero ring or aryl and Y as heterocyclic ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Hence the rejection is proper and is maintained.

This action is not made FINAL.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*V. Balasubramanian*  
VENKATARAMAN BALASUBRAMANIAN  
PATENT EXAMINER